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(71) Applicant: Pacesetter AB
171 95 Solna (SE)

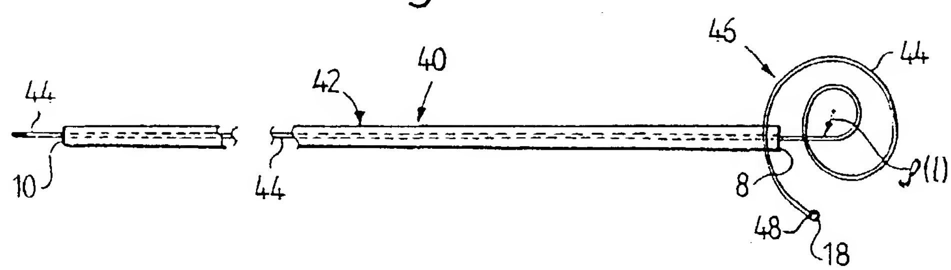
(72) Inventor: Boström, Mats
172 31 Sundbyberg (SE)

(74) Representative: Lettström, Richard Wilhelm
H. Albihns Patentbyra AB,
Box 3137
103 62 Stockholm (SE)

(54) Guide wire unit with internal guide wire of shape memory alloy

(57) A stylet unit (40), which can be inserted into a hollow, flexible component, such as an electrode cable, to stiffen the component and bend a distal end section thereof. The stylet unit (40) is a double stylet combination comprising a flexible tubular stylet shell (42) and an internal stylet wire (44), displaceably arranged inside the shell's channel, with a pre-bent distal end section (46). This end section can be set at a retracted internal position inside the stylet shell or at an exposed position outside the shell (42). The internal stylet's (44) pre-bent distal end section (46) is made of a shape memory alloy or metal and has a radius of curvature ($\rho(1)$) which varies longitudinally (1) in the section. The end section (46) can be devised in the shape of e.g. a spiral, and the shape memory alloy can be e.g. a nickel-titanium alloy.

Fig. 6



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Description

Field of the invention

The present invention relates to a stylet unit which can be inserted into a flexible component, such a hollow electrode cable, catheter or some other tubular instrument, with a narrow, longitudinal, internal channel to stiffen the flexible component and bend a distal end section of the component. The stylet unit constitutes a double stylet combination comprising a flexible, tubular stylet shell and an internal stylet wire, displaceably arranged inside the shell's channel, with a pre-bent distal end section which can be set to a retracted position inside the shell or to an exposed, external position outside the shell.

A channeled component of the aforementioned kind could e.g. be a tubular conductor used for stimulation in the human body. Such a channeled component could be devised to serve either as an implant or for removal from the body after a medical treatment has been performed.

The prior art

A stylet unit of the present kind is especially suitable for stiffening and guiding a hollow electrode cable for a heart stimulator during the electrode cable's advancement into a human heart and for anchoring a contact electrode (electrode head) on the distal end of the cable in a cavity of the heart. The introduction of such an electrode cable into the heart is usually through a suitable vein, and the contact electrode can be anchored either in the right ventricle or atrium. The temporarily introduced stylet unit inside the hollow electrode cable extends through the cable's central channel from the cable's proximal end (which is subsequently connected to the heart stimulator) to its distal end on which the contact electrode is located.

A stylet unit is especially suitable for anchoring a contact electrode in the heart's atrium, so a suitable J shape can be imparted to the distal end section of the electrode cable, thereby facilitating introduction of the end section into the atrial auricle and anchoring of the contact electrode in the trabeculae of the atrial auricle. After the contact electrode has been anchored at the desired site in the heart, the stylet unit is completely removed from the electrode cable which is then connected to the heart stimulator (e.g. a pacemaker) which is surgically implanted subcutaneously into the body, e.g. under the left pectoral muscle.

US A 5 170 787 describes and shows (see FIG. 2 in the document) a double stylet unit (referred to as a "double stylet wire"), i.e. a double stylet combination consisting of a flexible, tubular stylet shell containing a moveable, internal stylet wire in the shell's central channel. At the proximal end of this known stylet unit, there is a maneuvering handle with which the shell and the internal stylet can be moved in relation to each other for retracting the stylet wire's pre-curved distal end section into the surrounding shell's distal end section or for deploying the pre-curved distal end section of the stylet outside the opening of the shell's end section into the central channel of the distal end section of the surrounding electrode cable in order to give the distal end section the desired curved shape.

US A 4 136 703 shows another example of a stylet unit, devised as a double stylet combination, for an electrode cable. The stylet unit contains a pre-bent internal stylet wire in its distal end section. The stylet unit is inserted into a hollow, rather "limp" electrode cable in order to produce the required stiffening of the cable during the cable's introduction into the human body and, at the end of this introduction, achieve bending of the cable's distal end section equipped with a contact electrode. This cable bending is achieved when the stylet unit's internal stylet's pre-bent end section is switched from an inactive retracted position inside the shell to an exposed active position outside the opening of the shell. When the stylet's pre-bent end section inside the surrounding cable is exposed, the electrode cable is bent or curved to assume a desired J shape.

However, the types of prior art stylet units described in both the aforementioned US documents are incapable of insuring that the stylet unit - and accordingly its surrounding electrode cable - attains a desired, largely straight conformation when the internal stylet's pre-bent distal end section is retracted into its inactive, "parked" position inside the shell's corresponding distal end section.

US A 5 190 546 further describes medical applications (procedures and devices) involving the use of component means made of shape memory alloys or memory metals. The use of means made of voltage-induced martensite alloy, causing the thermal sensitivity of the said device to decline, thereby facilitating their introduction into or removal from the body of a human being or a mammal, is new and distinctive in these applications.

The procedures and devices set forth in the patent claims in the last patent document consistently involve attachment to or anchoring in bone in a body. The selected technic aims at preventing the memory metal from undergoing an undesirable martensitic phase shift because the memory metal's critical temperature is in about the same temperature range as bone/bony tissue in a living body.

Summary of the invention

A primary object of the present invention is to achieve a new type of stylet unit with which it is possible to attain a much straighter, i.e. with less lateral bending, and much better shape for the distal end section of the stylet shell in a stylet unit devised as a double stylet combination when all of the pre-bent distal end section of the moveable internal stylet wire has been retracted in-

side the shell's channel and surrounded by the stylet shell's enclosing distal end section.

When the stylet wire's pre-bent distal end section has been exposed and deployed outside the opening of the stylet shell, it produces the desired bending of a corresponding section of the narrow, channel-equipped flexible component, which holds and surrounds the stylet unit. This component could e.g. be (as noted above) a hollow cable, a catheter or some other kind of hollow, elongate instrument with relatively poor stiffness.

Since the stylet unit according to the invention is designed to stiffen a narrow, flexible component (into which the stylet unit is inserted) and bend a distal end section of this component, the invention's objective can also be said to be to provide a stylet unit for maneuvering a distal end section of a narrow, flexible component with an internal channel. When the component in question is a hollow electrode cable, intended for a heart stimulator or pacemaker, an object of the invention is also to offer a stylet unit with which it becomes possible to manipulate the distal end section of the electrode cable during implantation in the desired manner, i.e. from a virtually straight shape to a curved shape, the end section then being J-shaped.

As the aforementioned documents, which elucidate the prior art as regards stylet units, show, a typical stylet unit is made of thin-walled tubing and a pre-shaped stylet wire running inside the tube. When the stylet wire is moved in relation to the tube (with some kind of control mechanism), its exposed, pre-bent end section outside the end of the tube can be used to impart different shapes to surrounding electrode cable. The internal stylet in this known, typical stylet unit is usually made of stainless steel with a linear relationship between elongation and tension up to a maximum elongation of e.g. 3%. When the internal stylet's pre-bent, distal end section is retracted into the tubular stylet shell, the distal end section of the shell will acquire a lateral bulge because of the bending moment with which the successively retracted pre-bent end section exerts on the shell as the stylet wire is forced to straighten during retraction into the tubular shell.

As the above shows, however, keeping the stylet unit reasonably straight, even when the internal stylet's pre-bent distal end section has been fully retracted into the stylet shell, is very desirable. In practice, however, this desirable result cannot be achieved with the use of an internal stylet normally made of stainless steel, since straightening the internal stylet's pre-bent distal end section generates heavy flexural stress in the internal stylet, even when the magnitude of stretching is only 2-3%, as is attained even when there is a limited "straightening" of the internal stylet's pre-bent end section. The flexural stress, generated in the internal stylet when it is forced to straighten, imposes internal flexural stress, generated by the stylet, on the surrounding tubular stylet shell.

So an internal stylet made of stainless steel is not suitable in this context, since it subjects the surrounding tubular stylet shell to a bending moment so large that bulging of the stylet shell's end section cannot be avoided, even when the stylet only straightens to a modest degree. One essential objective of the present invention is therefore to select a material, other than stainless steel, which does not lead to inappropriately large flexural stress in the internal stylet wire, even when the stylet wire is exposed to maximum stretching exceeding the 3% value cited above for stainless steel.

An additional object of the invention is (as suggested above) to achieve a stylet unit whose internal stylet is able to bend a surrounding, hollow electrode cable enough for the distal end of the cable to assume a pronounced J shape or fish hook shape when all of the pre-bent distal end section of the stylet unit's internal stylet wire has been deployed outside the opening of the stylet shell. In order to achieve such a pronounced J shape for the end section of such a hollow electrode cable, into which the stylet unit according to the invention has been inserted, a stylet unit is required which is devised so the internal stylet wire is able to exert the largest possible bending moment on the surrounding stylet shell - and accordingly on surrounding electrode cable - even in the area in which the stylet shell's and the electrode cable's J-shaped bending begins.

The design problems related to the aforementioned objectives are solved according to the present invention primarily when the stylet unit of the aforementioned kind displays the distinguishing features set forth in patent claim 1.

Preferred embodiments and refinements of the stylet unit according to the invention can also display the distinguishing features set forth in the dependent patent claims.

The main distinctive feature of the stylet unit according to the invention is that the internal stylet's pre-bent distal end section is made at least in part of a shape memory alloy (memory metal) and comprises a stylet section whose radius of curvature varies longitudinally.

All of the internal stylet's pre-bent distal end section can be suitably made from shape memory alloy. From the fabrication point of view, it may be desirable for the stylet to be made entirely from shape memory alloy, not just its pre-bent distal end section.

For the internal stylet wire with its pre-bent distal end section to subject the tubular, surrounding stylet shell to a maximum bending moment right from the start of the radius of curvature, the stylet's pre-bent distal end section is preferably pre-bent with a radius of curvature whose magnitude increases longitudinally in the stylet section out towards its free end. This means that internal stylet's pre-bent distal end section must have its maximum curvature (i.e. its smallest radius of curvature) at the start of the pre-bent end section and then display decreasing curvature (i.e. an increasing radius of curvature) out towards the stylet section's free end

When the internal stylet wire's pre-bent distal end section is partially or wholly made of shape memory alloy or memory metal, far more efficient use of material is possible than is possible with conventional stainless steel since shape memory alloy (memory metal) enables the stylet's pre-bent distal end section to withstand maximum stretching up to e.g. 8%, when this end is retracted into the stylet shell, without the flexural stress caused by the stylet's straightening reaching values so high that the surrounding shell is forced to bulge laterally when the internal stylet's pre-bent end section is fully retracted into the stylet shell and, accordingly, fully straightened.

The use of a shape memory alloy in the stylet's pre-bent distal end section therefore makes it possible to use stylet material more efficiently than is the case when conventional stainless steel is employed. A memory metal (shape memory alloy) is then selected which displays pseudoelasticity in the temperature range anticipated for the stylet unit. The fact that the memory metal displays pseudoelasticity means that the metal can be deformed very considerably without any residual deformation after load relief.

An internal stylet wire made of memory metal therefore achieves the desired result that the internal stylet with its pre-bent distal end section acts on the surrounding stylet shell with a considerably lower bending moment when the stylet has been completely retracted into the shell than would be the case with the use of an internal stylet wire made of stainless steel.

When memory metal or shape memory alloy is used in the internal stylet's pre-bent distal end section, however, it must be remembered that this type of material has a much poorer ability to store energy than stainless steel. But this shortcoming can be overcome according to the invention when the internal stylet's pre-bent distal end section is devised so it exerts, when "straightened out", a bending moment on the stylet shell which is an appropriate function of the stylet's radius of curvature. This is achieved when the part of the stylet's pre-bent distal end section which is made of shape memory alloy, has a radius of curvature which varies longitudinally in the stylet. This is preferably attained when the memory metal stylet section is pre-bent with a radius of curvature whose magnitude increases longitudinally in the end section out towards the section's free end. One such radius of curvature is obtained e.g. when the stylet's pre-bent distal end section has a spiral shape, such as a hyperbolic or logarithmic spiral.

The memory metal or shape memory alloy used here is appropriately a nickel-titanium alloy, such as "Nitinol", which displays pseudoelasticity, at least in the 15°-45° C temperature range.

As examples of the dimensions of the internal stylet wire and the attendant stylet shell (in a stylet unit for an electrode cable) can be noted that a stylet wire diameter of about 0.20-0.25 mm may be appropriate when the diameter of the shell is 0.30-0.45 mm.

In order to insure that the relative movement between the internal stylet wire and the surrounding shell can be achieved without problems, with appropriate friction resistance, the gap, or tolerance, between these interacting components should appropriately amount to at least 0.02 mm.

Description of drawings

The invention will now be exemplified, described and explained in greater detail, referring to the attached drawings which display, in addition to an example of a known stylet unit, different aspects of the stylet unit and choice of material according to the invention. Thus:

FIG. 1 schematically shows the parts of a known stylet unit in which the internal stylet's pre-bent distal end section is deployed outside the opening of the stylet shell;
FIG. 2 shows the stylet unit depicted in FIG. 1 when the internal stylet's pre-bent distal end section is completely retracted into and surrounded by the tubular stylet shell's distal end section;
FIG. 3 shows stress-strain curves for stainless steel and memory metal respectively;
FIG. 4 shows the bent, distal end section of an electrode cable bent by means of a stylet unit;
FIG. 5 shows the distribution of bending moment for the bent electrode cable section shown in FIG. 4; and
FIG. 6 schematically depicts a stylet unit according to the invention when the internal stylet's pre-curved distal end section is completely outside the stylet shell's opening.

The preferred embodiment

FIGS. 1-2 schematically depict a distal end area of a known stylet unit 2, consisting of a double stylet design with a flexible, tubular stylet shell 4 and an internal stylet 6 which is moveable inside the shell's 4 channel. The distal end of the stylet shell 14 is designated 8, the proximal end of the shell is designated 10 and the proximal end of the stylet is designated 12. As shown in FIG. 1, the internal stylet 6 has a pre-bent distal end section 14 which, in the depicted example, mainly consists of a semicircular section with a radius of curvature ρ_1 and a short, straight stylet end section 16 with a stop ball 18 to prevent the end section 14 from being unintentionally retracted too far into the stylet shell 4 and to minimize the risk of the stylet end section 16 penetrating the wall of a surrounding electrode (not shown).

When the stylet unit 2 has been completely introduced into such a longitudinally hollow electrode cable (not shown), the pre-bent distal end section 14 in its exposed position induces the electrode cable's distal end section to assume a shape, as shown in FIG. 4.

FIG. 2 shows a section of the stylet unit 2 when the

internal stylet's 6 pre-bent distal end section 14 has been fully retracted into the stylet shell's 4 end section, causing the stop ball 18 to press against the opening at the tubular stylet shell's distal end 8. With semicircular shape for the stylet's distal end section 14 shown in FIG. 1, there is attendant lateral bulging or bending of the stylet shell's end section 4 - after the entire length of this end section has been retracted into and is enclosed in the stylet shell - whereby the shell end 8 will have a laterally projecting position corresponding to a lateral deviation L from the longitudinal axis A of the stylet unit's 2 straight tubular stylet shell 4, shown to the left in FIGS. 1-2.

Prior art stylet units shown in FIGS. 1-2 are made of metal, i.e. of stainless steel, whose stress-strain curve is shown in FIG. 3 in which it is designated 20. In the diagram in FIG. 3 the horizontal ∈ axis designates the current material's elongation expressed as a percent, whereas the vertical axis σ axis designates the material's stress, e.g. expressed in Mpa.

When the internal stylet's 6 pre-bent distal end section 14 is retracted into the stylet shell 4, the stylet shell causes the end section 14 to partially straighten, since the shell 4 is more resistant to bending than the stylet section 14. However, the shell is unable to straighten out the stylet section 14 completely, while retaining the entirely straight shape shown in FIG. 1, and the shell 4 itself acquires the bulge shown in FIG. 2. This bulging is caused by the bending moment exerted by the partially straightened stylet end section 14 on the surrounding part of the stylet shell 4. The lateral bulging of the stylet shell's 4 end section shown in FIG. 2 generates rise to the flexural stress in the material in the tubular stylet shell. The curve 20 in FIG. 3 illustrates the relationship between stress and strain for stainless steel of the kind used for both the internal stylet and the surrounding stylet shell in a known stylet unit of the kind shown in FIGS. 1-2. So flexural loading according to FIG. 2 generates very considerable flexural stress in the stylet shell 4, even when elongation only amounts to about 3%.

When the stylet unit 2 has been inserted into a hollow electrode cable 22 of the kind schematically depicted in FIG. 4 and when the stylet shell 4 and internal stylet 6 have been set to the position shown in FIG. 1, the hollow electrode cable 22 will have a curved distal end section 24 with the approximate shape shown in FIG. 4. In FIG. 4 an electrode contact head on the free end of the cable 22 has been designated 26 and four adjacent fins are designated 28.

If elementary beam bending theory is considered, it will be readily understood the cable is subjected to its maximum bending moment at about the section line X-X in FIG. 4 for the electrode cable's 22 end section to assume the curved shape shown in FIG. 4. This means that the exposed, pre-bent distal end section 14 of the stylet unit inserted into the cable must exert its maximum bending moment on the surrounding electrode cable at the beginning of its pre-bent distal end section, about at the section line X-X in FIG. 1.

The problem is then the aim at an internal stylet, whose pre-bent section 14 (in the position shown in FIG. 1) is to induce the electrode cable 22 to achieve a maximum bending moment at the section line X-X and (in the position shown in FIG. 2) without subjecting the surrounding stylet shell to a bending moment so great that the shell bulges into a shape like the one shown in FIG. 2. Instead it is desirable for the internal stylet 6, in the position shown in FIG. 2, to be largely incapable of bending the surrounding stylet shell 4 which should remain virtually straight even when the internal stylet 6 is fully retracted. However, these two desirable properties for the internal stylet are contradictory and cannot be successfully realized with a conventional stylet unit using a stylet made of stainless steel.

In order to achieve the said desirable properties for the internal stylet, the steel must be replaced with a material which is capable of withstanding much greater flexural stress and, accordingly, elongation (without being a plastic). It must also simultaneously generate much lower flexural stress when elongation is much greater.

As the general section of the above description shows, the problems can be effectively solved with a stylet unit in which the stylet's pre-bent distal end section is made wholly or partially of a shape memory alloy or memory metal at the same time as the end section has a varying radius of curvature.

FIG. 3 shows with bold contours the stress-strain characteristics for an appropriate shape memory alloy in this context. The curve 30 illustrates the ε-σ relationship when the load successively increases, whereas the tracing 32 shows the corresponding relationships when the load is successively reduced. FIG. 3 clearly shows that fabricating the internal stylet from an appropriate shape memory alloy or memory metal makes it possible to utilize the stylet material much better than when steel is used, since much greater elongation (e.g. 8%) is possible without strain approaching the strain achieved with steel when elongation only amounts to 3%. So the major advantage of an internal stylet made of shape memory metal or alloy is that the stylet will act on the surrounding stylet shell with a much lower bending moment (than if the stylet were made of stainless steel) when the stylet has been retracted back into the shell, corresponding to the situation depicted in FIG. 2. In order to simultaneously achieve an internal stylet wire which is capable of exerting the bending moment illustrated in FIGS. 4-5 on a surrounding electrode cable, the stylet's pre-bent distal end section must simultaneously be devised to be able to store the energy needed to produce the desired curvature of the electrode cable. According to the invention, this is achieved when the stylet's pre-bent distal end section has at least one stylet section whose radius of curvature varies in the section's longitudinal direction.

FIG. 6 shows an example of a stylet unit 40 accord-

ing to the invention. This stylet unit 40 comprises a flexible, tubular stylet shell 42 and a displaceable internal stylet 44. inside the shell's channel, with a pre-bent distal end section 46 made of a shape memory metal or alloy and whose radius of curvature ρ (1) increases in the section's longitudinal section 1 out towards the free end 48 of the stylet section.

The pre-bent distal stylet wire section 46 is shown in FIG. 6 in the form of a spiral-shaped, pre-bent distal end section.

So with a stylet unit 40 according to the invention, the bending moment M exerted by the internal stylet's 44 pre-bent distal end section 46 on the stylet shell 42 and hereby also on a surrounding electrode cable's 22 end section 24, will be a function of the stylet's radius of curvature ρ (1), i.e. M=f[ρ (1)]. In this manner, the internal stylet 44 is able to bend, using its exposed pre-bent end section 46, the surrounding electrode cable 22 into the J shape shown in FIG. 4 without acting on the stylet shell (in its retracted position corresponding to the situation depicted in FIG. 2) as heavily as would have been the case with a conventional stylet unit using an internal stylet made of stainless steel.

Finally, it should be noted that the pre-bent end section's 46 projection from and retraction into the stylet shell 42 is achieved in practice with a manipulation and holding device (not shown) arranged at the proximal end 10 of the shell 42. In practice, retraction of the internal stylet's 44 pre-bent end section 46 into the stylet shell 42 is appropriately achieved when the shell 42 is moved in relation to the stylet 44 towards the stylet section's 46 free end 48.

Claims

1. A stylet unit (40) which can be inserted into a flexible component, such as a hollow electrode cable, a catheter or some other tubular instrument, with a narrow, internal longitudinal channel, to stiffen the flexible component and bend a distal end section thereof, said stylet unit being a double stylet combination comprising a flexible, tubular stylet shell (42) and an internal stylet (44), displaceably arranged inside the shell's channel, with a pre-bent distal end section (46) which can be set to a retracted internal position inside the stylet shell or to an exposed, external position outside the shell, **characterized** in that the internal stylet's (44) pre-bent distal end section (46) is made at least in part of shape memory alloy and has a stylet section whose radius of curvature (ρ (1)) varies longitudinally (1).

2. A stylet unit according to claim 1, **characterized** in that the internal stylet's (44) pre-bent distal end section (46) is made wholly of shape memory alloy and is pre-bent with a radius of curvature (ρ (1)) whose magnitude increases longitudinally (1) in the section out towards the section's free end (48).

3. A stylet unit according to claim 1 or 2, **characterized** in that the entire internal stylet (44) is made of shape memory alloy.

4. A stylet unit according to claim 2 or 3, **characterized** in that the internal stylet's (44) pre-bent distal end section (46) has a shape approximating a spiral, e.g. a hyperbolic or logarithmic spiral.

5. A stylet unit according to any of the preceding claims, **characterized** in that the shape memory alloy is a nickel-titanium alloy, such as "Nitinol", and displays pseudoelasticity, at least in the 15° - 45° C temperature range.

Fig. 1

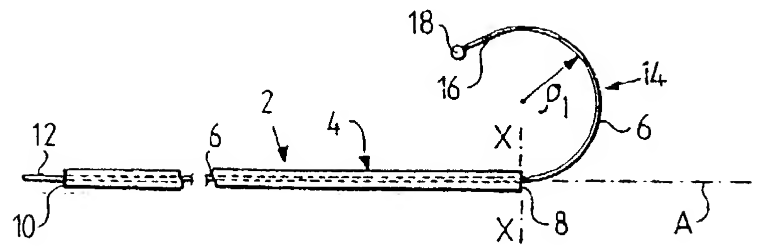


Fig. 2

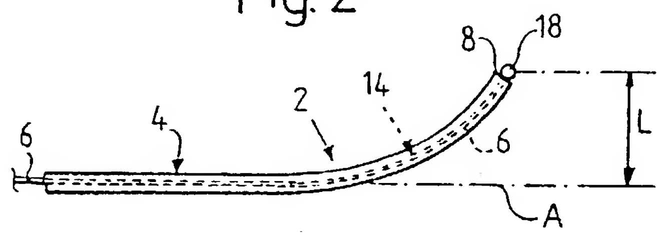


Fig. 3

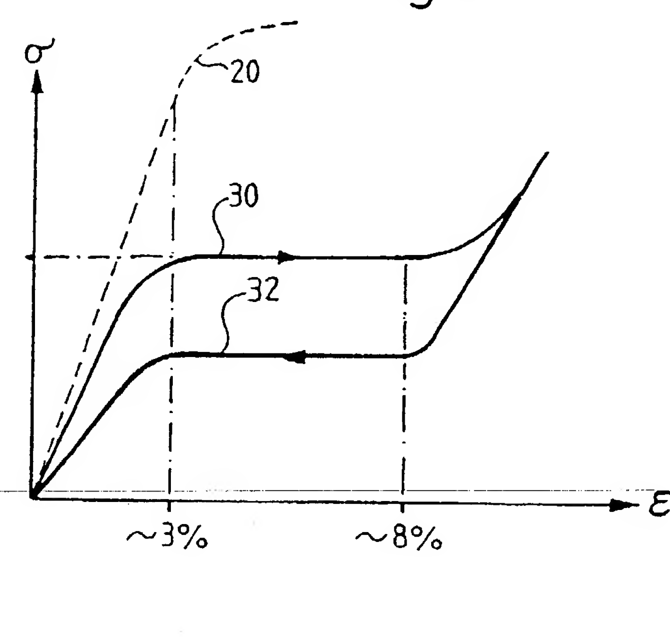


Fig. 4

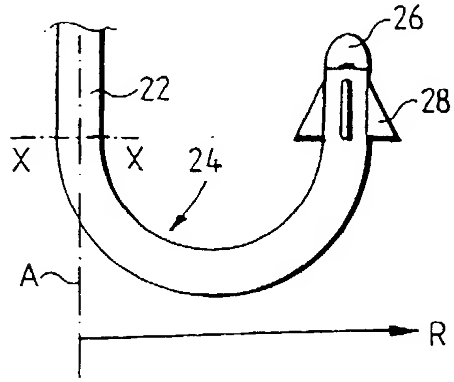


Fig.5

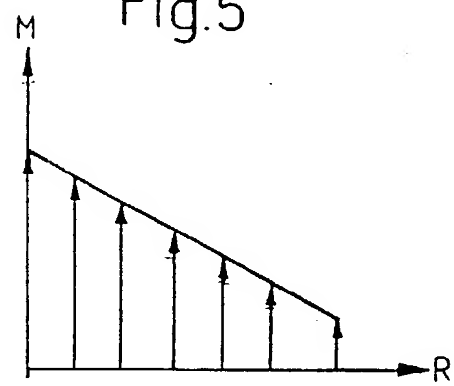
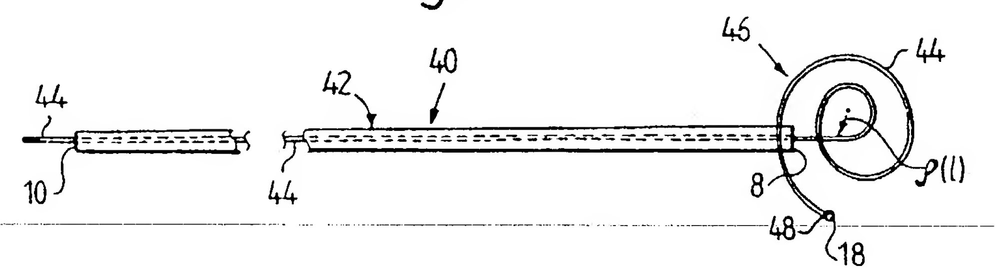


Fig. 6



European Patent Office

EUROPEAN SEARCH REPORT

Application Number
EP 96 85 0203.9

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.6)
X	EP, A1, 0381810 (ADVANCED CARDIOVASCULAR SYSTEMS, INC.), 16 August 1990 (16.08.90) * page 2, line 14 - line 36; page 3, line 9 - line 49, figures 1,4,5 *	1-5	A61M 25/09 A61N 1/05
A	WO, A1, 9013329 (PROGRESSIVE ANGIOPLASTY SYSTEMS, INC.), 15 November 1990 (15.11.90) * page 7, line 21 - page 9, line 6 *	1-5	
A	WO, A1, 9513111 (CARDIORHYTHM), 18 May 1995 (18.05.95) * page 8, line 26 - page 9, line 13, figure 1 *	1-5	
A	US, A, 5383923 (WILTON W. WEBSTER, JR.), 24 January 1995 (24.01.95) * abstract *	1-5	**TECHNICAL FIELDS SEARCHED (Int. Cl.6)** A61M A61N

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
STOCKHOLM	11 March 1997	EVA SELIN

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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